UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

In re WELLBUTRIN SR ANTITRUST LITIGATION	Civil Action No.: 04-cv-5898
THIS DOCUMENT RELATES TO:	COMPLAINT – CLASS ACTION
ALL END-PAYOR ACTIONS	

CONSOLIDATED SECOND AMENDED END-PAYOR CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiffs identified in paragraphs 9-14 herein ("Plaintiffs"), on behalf of themselves and all others similarly situated, hereby seek damages, other monetary relief and equitable relief for Defendants' violations of federal and state antitrust laws, state consumer protection laws and state common law principles of unjust enrichment. **Plaintiffs are mindful of this Court's November 2, 2009 ruling on Defendants' motion for judgment on the pleadings and reassert those causes of action dismissed by the Court for the limited purpose of preserving them on appeal, if any**. Plaintiffs respectfully request that the Court defer ruling on the New York claims alleged herein until such time as the United States Supreme Court rules in *Shady Grove Orthopedics Assocs., P.A. v. Allstate Ins., Co.*, 549 F.3d 137 (2d Cir. 2008), *cert. granted*, 129 S. Ct. 2160 (2009). Plaintiffs allege, upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, as follows:

INTRODUCTION

1. This litigation arises from a series of actions undertaken by Defendants GlaxoSmithKline plc, and SmithKline Beecham Corporation d/b/a GlaxoSmithKline Inc. (hereinafter sometimes collectively referred to as "Glaxo") to unlawfully maintain their monopoly on Wellbutrin SR ("Wellbutrin SR"). Faced with the threat of losing market exclusivity, Defendants engaged in a series of anticompetitive, and unlawful actions that ultimately extended exclusivity on the sale of Wellbutrin SR.

2. Wellbutrin SR is a sustained release antidepressant drug used to treat depression. The active ingredient in Wellbutrin SR is bupropion. For the 12 months ending June 30, 2002, domestic sales of Wellbutrin SR generated revenues in excess of $1.3 billion.

3. At least five manufacturers of generic drugs, including Eon Labs Manufacturing ("Eon"), Andrx Pharmaceuticals ("Andrx"), Watson Pharmaceuticals ("Watson"), IMPAX Laboratories ("IMPAX"), and Excel Pharmaceuticals ("Excel") filed applications with the FDA

requesting approval to market generic versions of Wellbutrin SR. In their applications, the manufacturers asserted that their products are "bioequivalent" to Wellbutrin SR and do not infringe any patent owned by or licensed to Defendants. Because of Defendants' actions, however, certain of these generic formulations were unlawfully delayed from coming to market.

4. Defendants unlawfully extended their monopoly in the United States Wellbutrin SR market by (1) making fraudulent statements to patent examiners during patent proceedings before the United States Patent and Trademark Office ("the PTO"); and (2) filing baseless patent infringement actions against manufacturers seeking to market a generic version of Wellbutrin SR based on (i) the fraudulently obtained patent and (ii) knowingly invalid and unsupportable claims of patent infringement under the Doctrine of Equivalents ("DOE").

5. Defendants sought to use one patent to delay entry into the market of competitors when Defendants knew that the patent did not cover those competitors' activities, and that the DOE was unavailable to them. Defendants sought to enforce a second patent that was obtained through fraud on the Patent Office and that Defendants knew was not enforceable. By enforcing these patents, Defendants initiated baseless litigation that no reasonable plaintiff could have expected to win in order to prevent generic pharmaceutical companies from entering the market for sustained release bupropion in violation of the Sherman Act.

6. As a result of their unlawful acts, Defendants have: (i) unreasonably restrained, suppressed and eliminated competition in the Wellbutrin SR market; and (ii) illegally maintained a monopoly in the Wellbutrin SR market. Plaintiffs bring their claims on behalf of all indirect purchasers of Wellbutrin SR, *i.e.* consumers and third-party payors, the last persons and entities in the chain of distribution, who purchased these prescription drugs other than for resale from March 1, 2002 to June 30, 2006 (the "Class Period").

7. Defendants' conduct has had far-ranging impact on consumers and third-party payors across the United States. The laws governing approval and marketing of pharmaceutical products are meant to balance the competing policy goals of providing new drug innovators an economic return on their investments while also ensuring consumers access to additional and more affordable generic versions of brand-name drugs. By engaging in anticompetitive conduct to prevent generic entry, Defendants effectively forced consumers to continue paying monopoly prices for Wellbutrin SR prescription products.

8. As a direct and proximate result of Defendants' unlawful conduct, consumers and third-party payors throughout the United States have been denied the benefits of free and unrestrained competition in the Wellbutrin SR market. Specifically, purchasers have been denied the opportunity to choose between the Wellbutrin SR brand name prescription products and generic versions of these medications which would have been priced well below Wellbutrin SR.

THE PARTIES

A. Third Party Payor Plaintiffs

9. Plaintiff IBEW - NECA Local 505 Health & Welfare Plan (the "IBEW Plan") is a welfare benefit plan with its principal place of business in Mobile, Alabama. The IBEW Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR during the Class Period other than for resale and were injured by the illegal conduct alleged herein. The IBEW Plan sustained injury when it purchased and/or provided reimbursement for Wellbutrin SR purchases in the states of Florida, Missouri, Louisiana, Oklahoma and Massachusetts.

10. Plaintiff Sheet Metal Workers Local 441 Health & Welfare Plan (the "Sheet Metal Workers Plan") is a welfare benefit plan with its principal place of business in Mobile,

Alabama. The Sheet Metal Workers Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR. During the Class Period, the Sheet Metal Workers Plan and its members were indirect purchasers of Wellbutrin SR and were injured by Defendants' unlawful conduct as alleged herein. The Sheet Metal Workers Plan sustained injury when it purchased and/or provided reimbursement for Wellbutrin SR purchases in the state of Florida.

11. Plaintiff MC - UA Local 119 Health and Welfare Plan (the "UA Plan") is a welfare benefit plan with its principal place of business in Mobile, Alabama. The UA Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR. During the Class Period, the UA Plan and its members were indirect purchasers of Wellbutrrn SR and were injured by Defendants' unlawful conduct as alleged herein. The UA Plan sustained injury when it purchased and/or provided reimbursement for Wellbutrin SR purchases in the states of West Virginia, Rhode Island, Georgia, Texas and Idaho.

12. Plaintiff A.F. of L. - A.G.C. Building Trades Welfare Plan (the "AFL Plan") is a welfare benefit plan with its principal place of business in Mobile, Alabama. The AFL Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR. During the Class Period, the AFL Plan and its members were indirect purchasers of Wellbutrin SR and were injured by Defendants' unlawful conduct as alleged herein. The AFL Plan sustained injury when it purchased and/or provided reimbursement for Wellbutrin SR purchases in the state of Florida.

13. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW ') is an "employee welfare benefit plan" and "employee benefit plan" UFCW's office from which it pays medical benefits, including benefits for prescription drugs, is located in Cook County, Illinois. During the Class Period, the UFCW Plan and its

members were indirect purchasers of Wellbutrin SR and were injured by Defendants' unlawful conduct as alleged herein. UFCW sustained injury when it purchased and/or provided reimbursement for Wellbutrin SR purchases in the states of Alabama, Arkansas, Arizona, California, Colorado, Florida, Iowa, Illinois, Indiana, Kentucky, Louisiana, Michigan, Minnesota, Missouri, Nevada, Oklahoma, Pennsylvania, Tennessee and Wisconsin.

14. Plaintiff Sidney Hillman Health Center of Rochester, Inc., is a multi-employer employee welfare benefit plan. During the Class Period, the Sidney Hillman Health Center was an indirect purchaser of Wellbutrin SR and was injured by Defendants' unlawful conduct as alleged herein. The Sidney Hillman Health Center sustained injury when it purchased and/or provided reimbursement for Wellbutrin SR purchases in the states of Florida, North Carolina and New York.

B. Defendants

15. SmithKline Beecham Corporation is a Pennsylvania Corporation with its principal offices located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham also conducts business in the name of GlaxoSmithKline Inc. and is a subsidiary of GlaxoSmithKline plc.

16. GlaxoSmithKline plc is a United Kingdom corporation with its principal offices located at Glaxo Wellcome House, Berkeley Avenue, Grenford, Middlesex, UB6 0NN, United Kingdom. GlaxoSmithKline was formed following the December 2000 merger of Glaxo Wellcome and SmithKline Beecham.

JURISDICTION AND VENUE

17. This Court has jurisdiction over this action pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1711, *et seq.*, which vests original jurisdiction in federal district court on any multi-state class action where the aggregate amount in controversy exceeds

$5,000,000 and the citizenship of any member of the class of plaintiffs is different from any defendant. The diversity and amount in controversy requirements of CAFA are satisfied in this case.

18. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and 15 U.S.C. § 22 because Defendants reside, transact business, are found, and/or have agents in this district, and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

FACTS

19. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. In 2001, sales of prescription drugs dispensed in the United States were approximately $153 billion. At all times pertinent herein, Defendants manufactured and sold Wellbutrin SR from their headquarters in Research Triangle Park, North Carolina.

20. In recent years, sales of Wellbutrin SR have generated billions in revenues for Defendants most of which was obtained by Defendants' unlawful suppression of generic equivalents.

A. The Federal Scheme For Approval Of Pioneer Drugs

21. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act"), approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "branded" drug, must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the

duration of the patents involved, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, codified at 21 U.S.C. § 355(j) (the "Hatch-Waxman Act") and 35 U.S.C. § 271(e).

22. In addition to information on safety and efficacy, NDA applicants must submit to the FDA a list of all patents that claim the drug for which FDA approval is being sought, or that claim a method of using that drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

23. Once the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), where it can be easily found and consulted by future FDA applicants.

24. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer obtains a new patent that claims the drug or methods of its use, the company must supplement its NDA by submitting information on the new patent within 30 days of issuance. The FDA then lists the new patent in a supplement to the Orange Book. The FDA is required to accept as true the patent information it obtains from patent holders, and to withhold its approval of a subsequent drug application, whenever the patent holder presents a litigated dispute (baseless or not) regarding the validity or infringement of the patent. If an unscrupulous patent holder provides false information to the FDA or files frivolous patent infringement actions to delay the onset of generic competition, the FDA is powerless to stop it.

25. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a

prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug that has been approved by the FDA is available.

B. Generic Drug Entry

26. Generic drugs are drugs that the FDA has found to be bioequivalent to brand name drugs, *i.e.*, generic drugs have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

27. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generic equivalents continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 15% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales. Unless the branded manufacturer lowers prices to meet competition, a branded drug loses a significant portion of its market share to generic competitors less than one year after the introduction of generic competition.

28. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers

whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing either the branded drug, or the AB-rated generic at a lower price.

29. Once a physician writes a prescription for a brand-name drug such as Wellbutrin, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs that carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

30. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, who are able to buy the same chemical substance at much lower prices. Many health insurance companies and employee benefit plans encourage or require substitution of generic drugs for brand-name drugs in order to lower health care costs. Retail pharmacies routinely substitute generic drugs for brand-name drugs whenever possible in order to lower their own costs and the costs of their customers.

C. Abbreviated New Drug Applications For Generic Drugs

31. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development, approval and marketing of generic drugs. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an "abbreviated" new drug application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted to the FDA by the company that manufactured the original, "pioneer" drug. The Act also provides an economic incentive to the manufacturer of the first generic drug to file an ANDA for a particular generic drug – *i.e.*, a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its drug free from other generic competition.

32. The most important new information that must be included in the ANDA concerns the generic company's position vis-a-vis the patent that the pioneer manufacturer

claims applies to the drug. Therefore, the ANDA filer must make one of four certifications to the FDA:

I. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

II. that the patent (or patents) for the pioneer drug has (or have) expired (a "Paragraph II Certification");

III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV certifications. *See id.* If the generic manufacturer makes a Paragraph IV Certification, the ANDA applicant must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vi)(IV).

33. The patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has a 45-day statutory period in which to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If no action is initiated within 45 days, FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the generic drug is automatically postponed until the earliest of: (i) the expiration of the patent; (ii) thirty months from the patent holder's receipt of the Paragraph IV Certification (30-month stay); or (iii) a final judicial determination of invalidity or non-infringement from which no appeal can be or has been taken. *Id.*; 21 C.F.R. § 314.107.

34. At all times relevant herein, under 21 U.S.C. § 355(j)(5)(B)(iv), the first applicant to submit an acceptable ANDA with a Paragraph IV Certification for a generic version of a brand-name drug receives a 180-day period of exclusivity before other ANDAs for the same drug can be approved by the FDA. The 180-day exclusivity period begins when the first ANDA applicant either (a) begins selling the generic drug or (b) obtains a final judgment of non-infringement in a patent infringement action, whichever occurs first. Thus, the first generic ANDA applicant has the opportunity to compete directly with the brand-name manufacturer for 180 days without competition from other generic manufacturers. If, however, the patent holder is able to forestall the events which trigger the start of the 180-day period of exclusivity, it can delay indefinitely the entry of all generic competitors.

D. The Development of Wellbutrin SR

35. Bupropion hydrochloride is an antidepressant used in the treatment of depression that is no longer subject to an extant patent. On June 25, 1974, the United States Patent and Trademark Office issued U.S. Patent No. 3,819,706 (the "'706 Patent"), granting to a predecessor of Defendants a compound patent on bupropion.

36. In the mid-1980s, the FDA granted to Defendants' predecessor approval to manufacture, market and sell bupropion hydrochloride under the brand name Wellbutrin. Defendants' predecessors, thereafter, began the manufacture, marketing and sale of Wellbutrin.

37. At that time, bupropion hydrochloride, or Wellbutrin, was sold in the form of an instant release tablet in which more than 75% of the bupropion was released from the tablet into dissolution media within about forty-five minutes. It was generally prescribed to be taken three or four times per day.

38. The '706 Patent expired in mid-1991. By that time, and for years before then, Defendants' predecessors had enjoyed a monopoly on the sale of bupropion through the manufacture, marketing and sale of Wellbutrin.

(i) The 1993 Sustained Released HPMC Patent Application

39. Subsequent to expiration of the '706 Patent, Defendants developed a sustained release version of bupropion which it markets as Wellbutrin SR. This formulation allows users of the drug to treat depression with only one or two daily doses.

40. In August 1993, Defendants' predecessor filed an application with the United States Patent and Trademark Office ("PTO") seeking patent protection for a controlled sustained release tablet containing bupropion (the "1993 SR Application").

(ii) Prosecution of the 1993 SR Application

41. The prosecution of the 1993 SR Application made evident the need for all claims to focus on, and be limited by, the significant role that hydroxypropylmethylcellulose ("HPMC") played in the invention.

42. On April 13, 1994, the examiner rejected Claims Fourteen, Fifteen and Nineteen of the Application for lack of enablement. Specifically the examiner wrote:

> The rate of release is directly related to the release retarding effect of hydroxypropylmethylcellulose. While other excipients have been disclosed, *the particular cellulose is considered critical for controlled and/or sustained release and should be incorporated into the independent claims.* The disclosure of a single species does not provide a basis for disclosing a generic concept . . . . (Emphasis added.)

43. In response, Defendants amended Claims Fourteen and Fifteen to recite that the tablets required HPMC. Defendants failed to amend Claims Eighteen and Nineteen at that time, but these claims were later amended by the examiner to identify the use of HPMC as the means for releasing bupropion.

44. Moreover, Defendants' proposed Claim One in the 1993 Application did not contain any recitations regarding bupropion release. The examiner, therefore, rejected this Claim for lack of enablement as well, noting that the claim needed to be limited:

> [A]pplicants are claiming a tablet that provides a distinct release profile. The advantage provided by the unique tablet *differ [sic] from the instant release tablet. The limitations of claims 2-3 are considered critical and should be incorporated into claim 1 for proper enablement.* (Emphasis added.)

45. In response, Defendants made similar amendments to Claim One, limiting it with the release controlling language.

46. The examiner's initial assessment of the 1993 SR Application was that the prior release controlling language in Claims One, Fourteen, Fifteen, Eighteen and Nineteen was too broad. By amending these claims (and indeed, by being forced to amend these claims), Defendants acknowledged and conceded that HPMC was the "particular cellulose that is critical for the controlled release of the tablets."

47. The PTO later mailed an Examiner's Amendment, which was authorized by counsel for Defendants, adding an HPMC limitation to another two claims in the 1993 SR Application. The PTO also issued a Notice of Allowability, signifying that the PTO's previous rejection of the claims would be withdrawn based on the addition of the HPMC limitation.

(iii) Issuance of the '798 Patent

48. Based on the prosecution history, including the examiner's analysis and the compulsory amendments, it was clear that the ultimate patent would cover HPMC as a control release agent.

49. On June 27, 1995 -- after the claims in the 1993 SR Application had been limited during patent prosecution -- the PTO issued Patent No. 5,427,798 (the "'798 Patent") entitled

"Controlled sustained release tablets containing bupropion." The '798 Patent was issued to Defendants' predecessor.

50. Glaxo describes the sustained release tablet claimed in the '798 Patent as follows:

> A controlled sustained release tablet having at least one year shelf life and containing bupropion hydrochloride, hydroxypropylmethylcellulose and cysteine hydrochloride or glycine hydrochloride with the tablet having a surface area to volume ratio to effectively control bupropion hydrochloride release in the body.

51. The patent specifications and patent prosecution history make clear that the '798 Patent is a narrow patent claiming a specific form of extended release tablet of bupropion which incorporates the excipient hydroxypropylmethylcellulose ("HPMC") as a control release agent.

52. Also clear both from the nature of the claims made in the '798 Patent, as well as from the patent prosecution history, is that HPMC as a release control agent is critical to the sustained release technology claimed by the '798 Patent.

53. Indeed, in its "*Brief Statement of Invention*," Glaxo notes that the purpose for the presence of HPMC is for "controlling drug release rate."

54. Glaxo knew that hydroxypropylcellulose ("HPC") had been recognized as a release controlling substitute excipient for HPMC when the patent application was filed and the '798 patent was issued. Glaxo also knew when this patent application was filed that polyvinyl alcohol ("PVA") could be used as a controlled released excipient.

55. Defendant supplied to the PTO information and documents describing the use of HPC and PVA as controlled release excipients on the Information Disclosure Statement required by the PTO during the prosecution of the '798 patent.

56. After limiting its claims, Glaxo could not broadly enforce the patent beyond the limitations established during the prosecution history. Under the legal doctrine of Prosecution History Estoppel or File Wrapper Estoppel, a patentee is not able to recapture subject matter

surrendered during prosecution of the patent by claiming that the surrendered material is an equivalent of the patented invention.

(iv) U.S. Patent No. 4,687,660 and Reissue Patent No. RE 33,994

57. Defendant's predecessor obtained U.S. Patent No. 4,687,660 ("the '660 patent") on Aug. 18, 1987. The '660 patent was reissued as U.S. Patent No. RE33,994 pm July 14, 1992 ("the '994 patent"). The claims of the reissued patent recited pharmaceutical compositions that resulted in a controlled release of bupropion in simulated gastric buffer.

58. Upon information and belief, Defendant violated its duty of candor to the PTO during the prosecution of the '994 patent by failing to disclose and/or misrepresenting to the patent examiner certain information material to the patentability of the '994 patent. Upon information and belief, Defendant was aware of such information and of its materiality before the issuance of the '994 patent and Defendant intended to deceive the PTO by withholding this information from the patent examiner.

(v) Wellbutrin SR Goes To Market

59. In October of 1996, the FDA granted final approval for Wellbutrin SR, and Defendants sought protection for the product by listing, among other things, the '798 Patent in the Orange Book. In February of 1997, Defendants began marketing 50 mg, 100 mg and 150 mg dosages of Wellbutrin SR.

C. The Doctrine of Equivalents

60. The DOE prevents the unscrupulous copyist from avoiding patent infringement by making unimportant and insubstantial changes to an invention in order to take the copied matter outside the scope of the claim and the law.

61. The general principle of the DOE is that if two inventions do the same thing in the same manner to yield the same result, then they are equivalent, even though they may differ in

name, form, or shape. If equivalence is found, a case for patent infringement may be made, despite the copyist's avoidance of the literal terms of the patent's claims.

62. The DOE has an important limitation, known as the Doctrine of Prosecution History Estoppel (or File Wrapper Estoppel), which states that a patentee may not use the DOE to recapture subject matter that the patentee surrendered during the prosecution of the patent by claiming that the surrendered material is an equivalent to an element of the patent invention.

D. Glaxo Unlawfully Suppressed Generic Competition For Wellbutrin SR By Instituting Sham Litigation

(i) ANDAs Submitted For Approval to Market Generic Versions of Wellbutrin SR and the Patent Infringement Actions

63. Several manufacturers of generic drugs filed ANDAs with the Food and Drug Administration seeking authorization to market generic versions of Wellbutrin SR. These companies include Andrx, Watson, Eon, IMPAX, and Excel.

64. While the patent claiming bupropion expired more than ten years ago, some of the claims of the '798 Patent claiming bupropion with HPMC in a sustained release formulation are still in effect.

65. Because utilization of the specific sustained release technology patented by Glaxo would constitute infringement of the '798 Patent, the above-referenced generic drug manufacturers have sought approval to market generic versions of Wellbutrin SR that utilized different sustained release formulations.

66. Eon, Excel, Impax and Watson sought approval of a bupropion sustained release tablet that does not use HPMC as a control release agent and, therefore, would not infringe upon any valid patent.

67. On June 18, 1999, Andrx submitted an ANDA for Wellbutrin SR 100 mg market. The FDA rejected the application insofar as it pertained to the market on the ground the application lacked safety information pertaining to Eudragit E 100.

68. In late July, 1999, the FDA informed Andrx that its ANDA application was not accepted for filing and requested additional information concerning the safety of Eudragit E 100. Before Andrx could submit the requested information, Watson submitted an ANDA for the Wellbutrin SR which was accepted by the FDA, thereby making Watson the first filer for the Wellbutrin SR market and entitling it to the 180 day exclusivity period afforded by the Hatch-Waxman Act.

69. Approximately 12 days after Watson submitted its ANDA application, Andrx submitted an amendment to its ANDA with the required safety information on Eudragit E 100. On August 27, 1999, the FDA informed Andrx of the acceptance of its ANDA as of the date of its August 12, 1999 filing.

(ii) The Infringement Actions and the Watson Litigation

70. The filing of a patent infringement action triggers a 30-month stay on the sale of generic versions pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay is triggered irrespective of whether there is any likelihood of success, or even merit, to the patent infringement action.

71. Defendants instituted a series of patent infringement actions that are objectively baseless and without merit for the purpose of triggering the 30-month stay and extending the time during which they enjoy complete exclusivity in the domestic market for Wellbutrin SR.

72. Glaxo has aggressively prosecuted the patent infringement actions in seeking to maintain their hold on the Wellbutrin SR market.

73. Defendants' lawsuits pressed the scope of the '798 Patent. In commencing these actions, Defendants ignored the express limitations that they knew had been imposed by the PTO in order to obtain issuance of the '798 patent. Defendants knew that litigation against the potential generic entrants was ultimately likely to fail.

74. Watson was the first-filer of an ANDA for 100 mg sustained-release bupropion hydrochloride.

75. Glaxo received notice of Watson's ANDA on October 26, 1999 and filed a patent infringement lawsuit against Watson on December 2, 1999.

76. A year and a half later, in July 2001, Glaxo settled its patent infringement lawsuit against Watson. Documents relating to the settlement and/or discontinuation of the action were filed under seal and are not publicly available.

77. Following the settlement with Glaxo, Watson relinquished its exclusivity rights to the 100 mg dosage of sustained-release bupropion hydrochloride.

(iii) The Eon ANDA and Patent Litigation

78. In July 2000, Eon submitted ANDA 75-932 seeking FDA approval to sell generic versions of Wellbutrin SR.

79. Eon's ANDA included a Paragraph IV Certification with regard to the '798 Patent claiming that its medication did not infringe on Glaxo's patent.

80. Eon's Paragraph IV Certification of non-infringement was predicated on the fact that its bupropion sustained release tablet did not utilize the HPMC release technology patented by Glaxo, but rather contained hydroxypropylcellulose ("HPC") as a control release agent.

81. On November 29, 2000, Glaxo sued Eon in the Southern District of New York claiming that Eon's generic Wellbutrin SR infringed two of its patents.

82. On August 13, 2003, the United States District Court for the Southern District of New York held on reconsideration that fact issues exist as to whether Glaxo was estopped from asserting infringement under the doctrine of equivalents. The court again denied Eon's summary judgment motion.

83. On August 22, 2003, the United States District Court for the Southern District of New York granted Eon summary judgment finding claim 1 of the '798 Patent invalid for lack of specificity and denied summary judgment as to the allegation that the entire patent is invalid by reason of overbroadness.

84. Notably on January 24, 2002, during the pendency of the litigation, Eon received tentative approval by the FDA to market its generic version of Wellbutrin SR utilizing the HPC sustained release formulation. Eon received final approval to enter the market on November 26, 2003.

85. Eon eventually received final approval in November, 2003 to market its bioequivalent generic version of Wellbutrin SR in the United States. But for the unlawful conduct of Defendants, Eon would have been able to market, distribute and sell a generic equivalent of Wellbutrin SR at least as early as January 24, 2002. Such conduct includes the filing of baseless lawsuits seeking to enjoin the generic manufacturers from producing bioequivalent generic versions of Wellbutrin SR on the grounds that these generics infringe upon Defendants' patents.

86. Eon did not enter the market until January 15, 2004. The delay of at least two years for the entry of a generic equivalent for Wellbutrin SR was directly and proximately the result of the unlawful conduct of Defendants.

(iv) The IMPAX ANDA and Patent Litigation

87. In August 2000, IMPAX Laboratories submitted an ANDA seeking FDA approval to sell generic versions of Wellbutrin SR.

88. Like Eon's ANDA, IMPAX's ANDA included a Paragraph IV Certification with regard to the '798 Patent which was predicated on the fact that IMPAX's proposed bupropion sustained release tablet utilized HPC as a control release agent, not HPMC.

89. On September 28, 2000, Glaxo sued IMPAX in the Northern District of California for infringement of its '798 Patent.

90. At the time Glaxo commenced the patent infringement action against IMPAX, it was aware, as it was at the time the '798 patent application was filed, that: (i) HPC had been recognized as a release controlling substitute excipient for HPMC; and (ii) by narrowing the patent claims during the prosecution, Glaxo abandoned any subject matter that existed between the original and amended claims.

91. IMPAX countered by arguing that its product did not use the HPMC sustained release technology patented by Glaxo, and moved for summary judgment on the grounds that the prosecution history precluded Glaxo from trying to claim HPC as being covered by the '798 Patent.

92. By substituting for the general means-function language originally included in the '798 Patent with a more specific HPMC limitation, Glaxo surrendered all equivalents of which it was or should have been aware and prosecution history estoppel barred infringement by the doctrine of equivalents.

93. Summary judgment was therefore granted to IMPAX on August 21, 2002.

94. In granting summary judgment, the Court rejected Glaxo's argument that it did not surrender claims to an HPC equivalent because it did not test HPC as an alternative excipient

in the bupropion sustained release tablets. The Court found that one skilled in the art would have known of the substitutability between HPMC and HPC for these purposes.

95. The Court also placed significance on the fact that Glaxo had obtained a patent for a sustained-release formulation comprised of both HPC and HPMC in January 1990. This fact seriously undermined any claim by Glaxo that it was unaware of HPC as a control release agent at the time it submitted and amended.

96. Glaxo appealed the Northern District of California's ruling in an attempt to preserve its market exclusivity and to dissuade IMPAX from bringing its product to market.

97. On January 29, 2004, the Court of Appeals for the Federal Circuit affirmed the grant of summary judgment in favor of IMPAX.

98. The Court further stated that the prosecution history shows that Defendant was well aware that HPC and PVA and numerous other polymers functioned in the manner of HPMC at the time the application was filed. The Court described the detailed information Defendant's submitted to the PTO on the Information Disclosure Statement and concluded that one of ordinary skill in the art at the time the application was filed would have considered these polymers suitable excipients in sustained release formulations and substantially equivalent to HPMC.

99. In early 2004, shortly after the Federal Circuit issued its decision in *Glaxo v. IMPAX*, involving facts virtually identical to those presented in the *Eon* lawsuit, Glaxo settled its claims against Eon. IMPAX was the first generic manufacturer to bring its 100 mg versions of Wellbutrin SR to the market.

100. On January 28, 2004, IMPAX received final FDA approval to enter the market with a 100 mg version of Wellbutrin SR.

(v) The Excel ANDA and Patent Litigation

101. In late 2001, Excel submitted an ANDA seeking FDA approval to sell generic versions of Wellbutrin SR. The release control excipient used in Excel's version of Wellbutrin SR was polyvinyl alcohol ("PVA"). On January 25, 2002, Glaxo brought a patent infringement suit in the Eastern District of Virginia against Excel, claiming that Excel's bupropion sustained release tablets infringed upon the '798 Patent.

102. The Court granted summary judgment to Excel on August 2, 2002. The court found that prosecution history estoppel prevented Glaxo from capturing PVA as an equivalent of HPMC. The ruling was remanded for additional fact finding by the Federal Circuit on January 29, 2004, before being voluntarily dismissed under Rule 41 of the Federal Rules of Civil Procedure by Glaxo on April 29, 2004.

103. Specifically, the Court found that Excel's generic version of Wellbutrin SR, utilizing PVA as a control release agent, did not literally infringe Glaxo's patent covering HPMC. When Glaxo commenced this action, it was aware that: (i) PVA was recognized as a release controlling excipient at the time the patent application was filed and the patent was issued; and (ii) by narrowing the patent claims during prosecution of the patent, Glaxo abandoned any subject matter that existed between the original and amended claims. Glaxo knew when it commenced the action that no equivalents existed for the invention of the '798 patent that would cover the use of PVA as a release controlling excipient.

(vi) The Andrx Patent Litigation

104. Glaxo brought suit against Andrx Pharmaceuticals, Inc. ("Andrx") for patent infringement in response to the filing of a Paragraph IV certification by Andrx stating that the use of a different grade of HPMC, i.e. a low viscosity, low molecular weight form of HPMC, did not infringe the '798 patent or that the patent was invalid.

105. On February 28, 2002, the United States District Court for the Southern District of Florida granted Andrx summary judgment holding that the patent was limited to the specific grade of HPMC in the specification and was not infringed by the Andrx ANDA.

106. Glaxo appealed the summary judgment grant to the United States Court of Appeals for the Federal Circuit. On September 22, 2003 the Federal Circuit held that the patent was not limited to the specific grade of HPMC described in the specification and the grant of summary judgment was vacated and remanded.

107. In May of 2004, without receiving payment of any kind from the defendant, Glaxo dismissed the lawsuit with Andrx.

E. The Elimination of Competition in the Sustained Release Buproprion Hydrochloride Market

108. The FDA's tentative approval letter to Eon in January, 2002 confirmed that Eon's generic product had been otherwise approved to go to market, but was prevented from doing so by legal impediments.

109. At this time, the only legal impediment to Eon's going to market with its 100 mg generic version of Wellbutrin SR was the 30-month stay in effect as a result of Defendants' baseless patent infringement suit against it.

110. Glaxo brought other patent infringement lawsuits against potential generic competitors to Wellbutrin SR which automatically triggered 30-month stays preventing entry by generic competitors with full knowledge that no equivalents were available for the HPMC claimed in the '798 patent.

111. In the *Andrx* suit, the district court awarded summary judgment in favor of Andrx, and the Court of Appeals for the Federal Circuit reversed. In the *Excel* suit, the Court found on summary judgment that Excel's generic version of Wellbutrin SR, utilizing PVA as a control

release agent, did not literally infringe Glaxo's patent covering HPMC. When Glaxo commenced the patent infringement action against Excel, Glaxo was aware, as it was at the time that it filed the '798 patent application, that: (i) polyvinyl alcohol was recognized as a release controlling excipient; and (ii) by narrowing the patent claims during prosecution, Glaxo abandoned any subject matter that existed between the original and amended claims.

112. In addition to IMPAX, Eon, Andrx, and Excel, Watson was the first company to submit an ANDA seeking FDA approval to sell 100 mg generic Wellbutrin SR. Watson later relinquished its first filer status entitling it to a 180 market exclusivity period under the Hatch Waxman Act. Thus, at the time Eon received tentative approval in January 2002, no generic manufacturer held marketing exclusivity rights for the 100 mg dosage.

113. In November 2003, the 30-month stay having expired, Eon sought and received final approval from the FDA for its generic version of sustained-release bupropion hydrochloride and announced that it would be bringing its product to market.

114. Glaxo sought to further delay Eon from bringing its generic to market by filing a request for an injunction in the United States District Court for the Southern District of New York in November 2003. This action was eventually resolved in favor of Eon, but there was a further delay of the market entry by of Eon.

115. Eon was finally able to bring its generic version of 100 mg sustained-release bupropion hydrochloride to market on January 15, 2004, approximately two years after it would have come to market if not for Defendants' unlawful acts.

116. The acts and practices of Defendants, as herein alleged, had the purpose and effect of injuring competition by unlawfully delaying the entry of generic Wellbutrin SR product into the relevant market.

117. Watson's settlement with Glaxo in July 2001 provided that Watson would be permitted to enter the market with a generic version of Wellbutrin SR manufactured by a Glaxo subsidiary as soon as another generic competitor entered the market. Therefore, but for Glaxo's unlawful filing of its meritless lawsuit against Eon, not only one, but at least two generic competitors to Wellbutrin SR would have entered the market in early 2002.

F. Defendant Obtained the '994 Patent Through Fraud on the PTO

118. Defendant fraudulently misrepresented facts material to patentability to the PTO to obtain the '994 patent.

119. The '994 patent is a reissue of the '660 patent.

120. A reissue patent examination is conducted when the patent holder petitions the PTO to remedy a defect in that patent that makes it fully or partially inoperative or invalid.

121. A patent re-examination may be requested by anyone who submits prior art patents and publications to the PTO that raise a substantial new question of patentability of the patent.

122. On August 18, 1987, Defendant's predecessor obtained the '660 patent. The six original claims of the '660 patent taught a mechanism for dispensing water soluble drugs over time and recited no claims to bupropion hydrochloride. Instead, the only mention of bupropion hydrochloride is found in the '660 patent specification examples describing time release methods: two using bupropion hydrochloride and one using pseudoephedrine.

123. Shortly after the '660 patent issued, and prior to the initiation of the reissue examination proceedings, Merck & Co. requested a re-examination of the '660 patent and specifically identified two prior art patents that rendered the '660 patent obvious and, therefore, not patentable.

124. On August 5, 1988, the PTO invalidated all of the original claims of the '660 patent as obvious in light of the newly submitted prior art. An advisory action upheld the

rejection of the '660's claims and the Defendant appealed to the Board of Patent Appeals and Interferences.

125. On August 4, 1989, while the '660 appeal was pending, and just before the bar date for submitting a broader reissue application, Defendant filed a fraudulent reissue application for the '660 patent. Defendant realized that the '660 patent would most likely be held invalid over the newly discovered prior art. The purpose of the reissue application was to save some of the patent coverage of the '660 patent. Therefore, Defendant concocted a story that highly desired claims to controlled release bupropion had been omitted and that this omission went unnoticed for nearly two years, even though for almost all of this two year period the patent had been involved in a reexamination procedure.

126. Under the statutory requirements and the regulations then in place, to request a reissue examination, the patent holder must assert not only that (a) there was an error made during the prosecution of the patent that makes it fully or partially inoperative or invalid; but also (b) must specifically under oath or by declaration indicate (i) the exact error, (ii) when and how the error was made, and (iii) when it was discovered. The reissue application must also present evidence of the inventor's original intent to include new claims omitted from the original patent. *See* 35. U.S.C. §251; 37 C.F.R 1.175; 37 C.F.R. 1.63, 1.66, 1.68.

127. In support of its reissue application, Defendant asserted that the original patent mistakenly failed to address the highly desired claims of a sustained release bupropion compound.

128. In its original reissue application, Defendant failed to file the affidavit of error and intentionally withheld material information from the PTO. Defendant sought to amend the '660 patent to claims describing a sustained release bupropion hydrochloride composition "in a solid

sustained release pharmaceutical carrier with particular limiting testing conditions," rather than the original claims which extended to a time release mechanism to deliver a much wider class of drugs.

129. On June 18, 1990, the PTO summarily rejected Glaxo's amended claims as obvious under 35 U.S.C. §103 and indefinite under 35 U.S.C. §112 because the claims were unduly broad in the phrase "controlled release composition" and because Glaxo failed to file the required affidavit of error.

130. In a second attempt to obtain the reissue patent, Glaxo submitted an unsworn statement that the defect in the '660 patent arose because the Defendant claimed less than they could have claimed. Again, Defendant failed to inform the PTO of the different facts it already knew surrounding the '660 patent history. This time Defendant amended the claims to add dissolution testing parameters.

131. On November 6, 1990, the PTO rejected those amended claims again because (1) the Defendant failed to state the error as required by 37 C.F.R 1.175 and (2) these new claims failed to satisfy 35 U.S.C. §112 because the specification and its examples did not provide support for the invention as it was now claimed in the amended reissue petition.

132. On December 21, 1990, Glaxo once again replied to the PTO and finally submitted a sworn statement from the '660 inventors, which pointed out the two bupropion hydrochloride examples in the patent specification. The inventors claimed that the errors occurred because during the '660 patent prosecution, Glaxo and the inventors were concentrating their efforts on the patenting of the tablet (Claims 1 through 4) and composition (Claims 5 through 6) and forgot to claim the sustained-release nature of the composition of the particular compound of Examples 1 and 3. The declaration states that the inventors, assignee (Defendant),

and counsel held conferences to review the specification and determine that such compositions could have been claimed. Glaxo withheld material information from the PTO by failing to identify the real reason for the reissue application.

133. The PTO rejected this attempt to satisfy the requirements for a reissue application on May 6, 1991, as unspecified and failing to properly describe the error to justify a reissue patent as required by 37 C.F.R. 1.175.

134. On August 9, 1991, Glaxo submitted yet another supplemental reissue declaration with a copy of the previously filed and rejected statement of errors.

135. On September 17, 1991, the PTO rejected Glaxo's third attempt to obtain the reissue patent because Glaxo failed to establish the intent to prosecute new claims and because this third petition (the second supplement to the original) again contained insufficient explanation of how the error arose, when it was discovered and who discovered it.

136. On December 5, 1991--over two years after Defendant first requested the reissue patent--Glaxo submitted a third supplemental declaration containing another declaration from the inventors pointing to the two bupropion hydrochloride specification examples and for the first time proferring an explanation. The declaration falsely stated that the error occurred because Glaxo's technical staff failed to inform its patent attorneys that claims specific to bupropion hydrochloride were important. The inventors also stated that Glaxo's patent attorney first discovered the error in the spring of 1989, researched the error during the summer and fully understood the error before Glaxo filed its original reissue application on August 4, 1989. Defendant also amended the new claims again, this time incorporating the exact claim language from the PTO's latest rejection. That language then became the new claim 7 of the '994 reissue patent when the '994 patent eventually issued on July 14, 1992.

137. It is clear that during the reissue procedure, Defendant decided that the claims that had issued in the '660 patent, and that were also at issue in the reexamination, were no longer of interest (in large part due to the fact that the '660 patent was going to be found invalid) and cancelled all of them, electing to concentrate on the newly discovered claims. It is also clear that the examiner was not going to allow the reissue patent to issue with only Glaxo's bare statement that there was an error in prosecution of the '660 patent. In order to succeed on the reissue application, Glaxo had to fraudulently allege that the claims specific to bupropion hydrochloride had been "accidentally" omitted in the '660 patent. Glaxo further had to fraudulently concoct a cover story explaining how a sophisticated patentee and experienced patent counsel could have mistakenly prosecuted an undesired patent and take over two years to discover this error, and then an additional two years and several legally deficient statements to articulate this supposed error to the PTO.

138. The declarations filed by the inventors include acknowledgements that the inventors reviewed and understood the contents of the specification and revised claims before they signed the declaration; that statements made by the inventors are made of their own knowledge and are true; that statements made on information and belief are believed to be true; and that willful false statements are punishable by fine or imprisonment under 18 U.S.C. 1001 and jeopardize the validity of the patent or application.

139. In the Declaration of December 1990, the inventors declared that conferences were held with counsel and the assignee (Defendant). However, in their deposition testimony in the *Andrx* case, neither Inventor Baker nor Brooke recalled participating in conferences regarding this reissue application at that time.

140. In the Declaration of November 1991, the inventors declare that they were informed by Donald Brown that the PTO had determined that their prior declarations were insufficient to establish intent to claim the subject matter sought in the reissue application and provided insufficient explanations as to the how the error arose, when it was discovered, and who discovered the error. The inventors' declaration also repeatedly stated that Donald Brown informed them of the various facts about the error and the intent of Glaxo to claim the bupropion hydrochloride controlled release composition.

141. In sworn deposition testimony provided in the *Andrx* case, neither inventor recalled discussing the insufficiency of their previous declaration with either Donald Brown or with any of the other attorneys identified in the Declaration of November 1991. Inventor Brooke recalled only that the declarations needing his signature were handed to him by an administrative assistant, with there being no discussion as to what he was signing or why he was signing it.

142. The '994 patent would not have issued absent Glaxo's fraud on the PTO. The fraudulent acts were orchestrated and controlled by unknown persons at Glaxo and implemented by its agent, the patent attorney that prosecuted the patents at issue.

G. Glaxo Used the Fraudulently Obtained '994 Patent To Unlawfully Extend Its Monopoly Power

143. As part of its exclusionary scheme to monopolize, Glaxo used its fraudulently-obtained patent and sham litigation to delay generic entry and thereby unlawfully protect and maintain its monopoly power with respect to bupropion SR products. By delaying generic entry, Glaxo preserved the power to price bupropion SR products substantially above competitive levels, and forced purchasers to pay substantially more for bupropion SR products than they otherwise would have paid. Specifically, Glaxo used the fraudulently-obtained '994 patent to

engage in sham litigation against EON in order to delay EON's entry with a competing generic bupropion SR product.

144. On July 26, 2000, EON submitted an ANDA seeking to market a generic version of Wellbutrin SR. The ANDA contained a Paragraph IV certification that the '994 patent was invalid and/or not infringed by EON's product.

145. On November 29, 2000, Glaxo filed suit in the United States District Court for the Southern District of New York against EON, a generic drug manufacturer, for infringing the '994 patent by submission of an ANDA proposing their marketing of a controlled release bupropion compound.

146. By initiating this litigation, Glaxo received the 30 -month stay preventing EON from receiving final FDA approval to market generic Wellbutrin.

147. On January 24, 2002, EON received tentative approval for the generic Wellbutrin ANDA submitted on July 26, 2000. Absent the litigation, EON would have been able to launch its generic bupropion product in January 2002 or shortly thereafter.

148. On August 13, 2002, the United States District Court for the Southern District of New York granted EON's motion for partial summary judgment on the '994 patent. The court held that the '994 patent was invalid because a person skilled in the art would not be able to practice the invention to the full extent of the specification.

149. Glaxo not only knew at the onset of the litigation that the '994 patent was unenforceable, but, then proceeded to assert the fraudulently obtained '994 patent in order to invoke the 30-month Hatch-Waxman stay. These actions prevented a generic version of bupropion from coming to market and consequently illegally extended Glaxo's monopoly on Wellbutrin SR and its generic equivalents while the litigation progressed.

150. Sometime after the court's grant of partial summary judgment, Glaxo delisted the '994 patent from the Orange Book. After the 30-month stay expired in November 2003, EON received final approval of the generic Wellbutrin SR ANDA from the FDA and announced that the product would be marketed. This announcement was made even though Glaxo continued to prosecute the patent infringement litigation against EON.

151. Glaxo responded to Eon's announcement by moving for a temporary restraining order ("TRO"), which was granted on November 26, 2003, and then extended on December 12, 2003.

152. While the TRO was in place, the district court held a bench trial and converted the TRO into a preliminary injunction.

153. EON immediately appealed the preliminary injunction, and on January 14, 2004, the Federal Circuit entered an order staying the preliminary injunction.

154. On January 15, 2004, Eon launched its generic bupropion product, which was the first to enter the market.

155. Shortly thereafter, the Federal Circuit affirmed the grant of summary judgment in the Impax case described above, which raised nearly identical issues as in the Eon case since Impax and Eon's products used the same excipient, HPC.

156. Glaxo voluntarily dismissed the Eon litigation in April 2004, only after it became clear that Glaxo could no longer block generic competition through the process of litigation.

157. If not for the 30-month stay invoked by Glaxo filing the baseless EON litigation and the additional period of exclusivity gained for Glaxo by obtaining an improper injunction, EON would have been able to market generic Wellbutrin on March 1, 2002, nearly two years earlier than they actually began marketing the drug.

158. Defendants have engaged in monopolistic practices concerning Wellbutrin SR to avoid a loss in market share and revenues that would inevitably result following the introduction to the market of a competing generic product.

159. If generic competitors had not been unlawfully prevented from entering the relevant market and competing with Defendants, consumers and third-party payors such as Plaintiffs would have been free to substitute a lower-priced generic for the higher-priced brand name drug and would have paid less for Wellbutrin SR.

160. Indeed, Defendants have corporate policies to extend and abuse the legitimate range of U.S. patent laws, and Defendants' attempted extension of the Wellbutrin SR monopoly is part of the pattern and practices of Defendants. For instance, the Federal Circuit Court of Appeals affirmed a District Court verdict that Defendants' patent for the anti-inflammatory prescription drug nabumetone -- which it markets under the brand-name Relafen -- was invalid. *In re '639 Patent Litig.,* 154 F. Supp. 2d 157 (D. Mass. 2001), *aff'd sub nom. Smithkline Beecham Corp. v. Copley Pharm.,* 2002 U.S. App. LEXIS 16594 (Fed. Cir. Aug. 15, 2002). In that case, the District Judge found that SmithKline Beecham had "engaged in a pattern of misrepresentation in its dealings with the PTO so pervasive as to negate any possibility that Beecham's misrepresentations to the PTO were inadvertent 'loose language' or otherwise 'negligently made'." *Id.* at 66. The Court there also found Beecham's witnesses "to be inconsistent, evasive and, many times, implausible." *Id.* at 193-94. The Court further found that Beecham was attempting to persuade the PTO that there was no prior art anticipating its patent, while evidence before the Court revealed that Defendant's patent department knew this was not the case, and could not believe their success in getting the patent approved, and were happy that they had "put one over on" the PTO. *Id.* at 194.

161. If a generic competitor had been able to enter the relevant market and compete with Defendants, consumers and third-party payors such as Plaintiffs would have been free to substitute a lower-priced generic for the higher-priced brand name drug and the Class would have paid less for Wellbutrin SR products. Pharmacists generally are permitted, and in many instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payors of prescription drugs (*e.g.*, managed care plans) encourage or insist on the use of generic drugs whenever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year.

162. By preventing generic competitors from entering the market, Defendants injured Plaintiffs and the other Class members in their business or property by causing them to pay more for Wellbutrin SR products than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiffs and other members of the Class of the benefits of competition that the antitrust laws and applicable state consumer protection laws were designed to preserve.

INTERSTATE TRADE AND COMMERCE

163. At all times relevant herein, Defendants manufactured and sold substantial amounts of Wellbutrin SR in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States as follows:

- Defendants transmitted funds as well as contracts, bills, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Wellbutrin SR; and

- Defendants employed, in furtherance of their monopolization and attempt to monopolize, as alleged herein, the United States mails and interstate and international telephone lines as well as means of interstate and international travel.

164. The illegal monopolization and attempt to monopolize the markets for Wellbutrin SR as alleged herein have substantially affected interstate and foreign commerce.

RELEVANT MARKET

165. The relevant product markets is Wellbutrin SR and its generic bioequivalents rated "AB" by the FDA. The relevant geographic market is the United States. Defendants' market share in the relevant product and geographic markets was 100%. Since January 2004, when generics were finally able to come to market, Defendants market share eroded due to increasing generic competition.

CLASS ACTION ALLEGATIONS

166. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, specifically Rules 23(b)(2) and 23(b)(3), on behalf of the following class (the "Class"):

> All persons and entities in the United States who, at any time from March 1, 2002 to June 30, 2006, purchased 100 mg and/or 150 mg Wellbutrin SR and/or their generic equivalents for purposes other than resale. Excluded from the Class are the Defendants, their subsidiaries and affiliates, government entities and any person or entity that purchased Wellbutrin SR directly from Defendants. For purposes of the Class definition, persons and entities "purchased" Wellbutrin SR if they paid some or all of the purchase price.

167. Plaintiffs believe, and therefore aver, that there are thousands of members in the above-described class; their exact number and identities being currently unknown to Plaintiffs, but known to Defendants and/or ascertainable from appropriate discovery.

168. Among the questions of law and fact common to the Class are:

(a) Whether Defendants have unlawfully monopolized or attempted to monopolize the market for Wellbutrin SR;

(b) Whether Defendants possessed and/or unlawfully extended their monopoly power over the market for Wellbutrin SR;

(c) Whether Defendants, through their monopolization and/or attempted monopolization, have caused the prices of Wellbutrin SR to be maintained at supracompetitive levels;

(d) Whether Defendants' patent infringement lawsuits against Eon and IMPAX to prevent them from entering the market with a lower priced therapeutically equivalent version of Wellbutrin SR constitutes unlawful conduct;

(e) Whether the Class suffered antitrust injury; and

(f) Whether Defendants were unjustly enriched to the detriment of the Class, entitling Plaintiffs and the Class to disgorgement of all monies resulting therefrom.

169. Plaintiffs' claims are typical of the Class because Plaintiffs and all members of the Class were injured in the same manner by Defendants' unlawful, anticompetitive and inequitable methods, acts and practices, and wrongful conduct complained of herein, *i.e.,* Plaintiffs and all members of the Class have paid supra-competitive and artificially high prices for Wellbutrin SR.

170. Plaintiffs willfully and adequately protect the interests of all members of the Class. Plaintiffs have retained counsel who are experienced in antitrust class action litigation. Plaintiffs have no interests which are adverse to, or in conflict with, other members of the Class.

171. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members.

172. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The Class is readily definable and prosecution as a class action

will eliminate the possibility of duplicative litigation, while also providing redress for claims which would otherwise be too small to support the expense of individual, complex litigation.

173. Defendants have acted or refused to act, as alleged herein, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief and/or corresponding declaratory relief with respect to the Class as a whole.

COUNT ONE

A. For Monopolization Under State Law

174. Plaintiffs incorporate by reference the preceding allegations.

175. Plaintiff IBEW Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Florida and Massachusetts.[1]

176. Plaintiff Sheet Metal Workers Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the state of Florida.

177. Plaintiff UA Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the state of West Virginia.

178. Plaintiff AFL Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the state of Florida.

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[1] Plaintiffs have attached a chart as Exhibit A detailing those states where each named plaintiff purchased and/or made reimbursement for Wellbutin SR.

179. Plaintiff UFCW brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Arizona, California, Florida, Michigan, Minnesota, Nevada and Wisconsin.

180. Plaintiff Sidney Hillman Health Center brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Florida, North Carolina and New York.

181. As described above, Defendants knowingly and willfully engaged in a course of conduct designed to extend their monopoly power. This course of conduct included, *inter alia*, improperly filing patent infringement actions against generic manufacturers seeking to obtain approval to sell generic versions of Wellbutrin SR.

182. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Arizona Revised Stat. §§ 44-1401, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in Arizona by Plaintiff UFCW and similarly situated members of the Class.

183. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and Cal. Bus. & Prof. Code §§ 17200, *et seq.* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in California by Plaintiff UFCW and similarly situated members of the Class.

184. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Fla. Stat. §§ 501. Part II, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in Florida by Plaintiffs IBEW Plan, Sheet Metal Workers Plan, AFL Plan, UFCW, Sidney Hillman Health Center and similarly situated members of the Class.

185. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Mass. Gen. Laws ch. 93A, *et seq.*, with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in Massachusetts by Plaintiff IBEW Plan and similarly situated members of the Class.

186. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Mich. CompLaws Ann. §§ 445.771, *et seq.*, with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in Michigan by Plaintiff UFCW and similarly situated members of the Class.

187. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Minn. Stat. §§ 325D.52, *et seq*. with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in Minnesota by Plaintiff UFCW and similarly situated members of the Class.

188. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Nev. Rev. Stat. Ann. § 598A., *et seq.*, with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in Nevada by Plaintiff UFCW and similarly situated members of the Class.

189. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of New York General Business Law § 340, *et seq*., with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in New York by Plaintiff Sidney Hillman Health Center and similarly situated members of the Class.

190. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases

and/or reimbursements for purchases of Wellbutrin SR in North Carolina by Plaintiff Sidney Hillman Health Center and similarly situated members of the Class.

191. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of W.Va. Code §§ 47-18-1, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in West Virginia by Plaintiff UA Plan and similarly situated members of the Class.

192. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in Wisconsin by Plaintiff UFCW and similarly situated members of the Class.

193. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for Wellbutrin SR prescription drugs than they would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of the above states were designed to prevent and flows from that which makes Defendants' conduct unlawful.

194. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT TWO

A. For Unfair And Deceptive Trade Practices Under State Law

195. Plaintiffs incorporate by reference the preceding allegations.

196. Plaintiff IBEW Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Florida, Missouri, Oklahoma and Massachusetts.

197. Plaintiff Sheet Metal Workers Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the state of Florida.

198. Plaintiff UA Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Rhode Island and Idaho.

199. Plaintiff AFL Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the state of Florida.

200. Plaintiff UFCW brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Arkansas, Arizona, California, Colorado, Florida, Michigan, Minnesota, Missouri, Nevada, Oklahoma, and Pennsylvania .

201. Plaintiff Sidney Hillman Health Center brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Florida, North Carolina and New York.

202. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they filed baseless patent infringement actions against Eon and IMPAX and other generic manufacturers in order to prevent the FDA from granting final approval of pending applications of would-be competitors to market generic Wellbutrin SR. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and class members were deprived of the opportunity to purchase a generic version of

Wellbutrin SR, from March 1, 2002 until January 2004, and forced to pay higher prices for Buproprion Hydrochloride SR from January 2004 to June 30, 2006.

203. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq*.

204. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq*.

205. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq*.

206. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq*.

207. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.

208. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.

209. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq*.

210. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq*.

211. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, *et seq*.

212. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Missouri Stat. § 407.010, *et seq*.

213. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 41.600, *et seq*.

214. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 *et seq*.

215. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq*.

216. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, *et seq*.

217. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq*.

218. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq*.

219. Plaintiffs and members of the class members have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for Wellbutrin SR prescription drugs than they would have paid in the absence of these violations. This injury is of the type the referenced state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT THREE

A. Unjust Enrichment

220. Plaintiff IBEW Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Florida, Missouri, Louisiana, Oklahoma and Massachusetts.

221. Plaintiff Sheet Metal Workers Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the state of Florida.

222. Plaintiff UA Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of West Virginia, Rhode Island, Georgia, Texas and Idaho.

223. Plaintiff AFL Plan brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the state of Florida.

224. Plaintiff UFCW brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Alabama, Arkansas, Arizona, California, Colorado, Florida, Iowa, Illinois, Indiana, Kentucky, Louisiana, Michigan, Minnesota, Missouri, Nevada, Oklahoma, Pennsylvania, Tennessee and Wisconsin.

225. Plaintiff Sidney Hillman Health Center brings this count on its own behalf and on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Florida, North Carolina and New York.

226. Defendants have benefited from the monopoly profits on their sales of Wellbutrin SR resulting from the unlawful and inequitable acts alleged in this Complaint.

227. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Wellbutrin SR by Plaintiffs and members of the Class.

228. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

229. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for Wellbutrin SR is a direct and proximate result of Defendants' unlawful practices.

230. The financial benefits derived by Defendants rightfully belong to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

231. It would be inequitable and violative of the laws of the states named within this count concerning unjust enrichment for the Defendants to be permitted to retain any of the overcharges for Wellbutrin SR derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

232. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.

233. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

234. Plaintiffs and the Class have no adequate remedy at law.

COUNT FOUR

A. For Monopolization Under State Law On Behalf Of Class Members In States Where Named Plaintiffs Did Not Purchase Or Provide Reimbursement For Wellbutrin SR.

235. This count is brought solely to preserve the appellate rights of the Plaintiffs in light of Judge Stengel's November 2, 2009 Memorandum and Order in this action.

236. This count is brought on behalf of a subclass comprised of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Kansas, Maine, Mississippi, Nebraska, New Mexico, North Dakota, South Dakota, Utah, Vermont and the District of Columbia, where the named Plaintiffs did not purchase and/or provide reimbursement for purchases of Wellbutrin SR. Plaintiffs allege that they are adequate class representatives for class members affected in these jurisdictions pursuant to Fed. R. Civ. P. 23.

237. As described above, Defendants knowingly and willfully engaged in a course of conduct designed to extend their monopoly power. This course of conduct included, *inter alia*, improperly filing patent infringement actions against generic manufacturers seeking to obtain approval to sell generic versions of Wellbutrin SR.

238. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of D. C. Code Ann. §§ 28-45031 *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the District of Columbia by members of the Class.

239. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Kan. Stat. Ann. §§ 5-101, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the state of Kansas by members of the Class.

240. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the state of Maine by members of the Class.

241. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Miss. Code Ann. §§ 75-21-1, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the state of Mississippi by members of the Class.

242. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Neb. Code Ann. §§ 59-801, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the state of Nebraska by members of the Class.

243. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N. M. Stat. Ann. §§ 57-1-1, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the state of New Mexico by members of the Class.

244. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N. D. Cent. Code § 51-08.1-01, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the state of North Dakota by members of the Class.

245. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of S. D. Codified Laws Ann. § 37-1, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the state of South Dakota by members of the Class.

246. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Utah Code Ann. §§ 76-10-911, *et seq.,* with respect to

purchases and/or reimbursements for purchases of Wellbutrin SR in the state of Utah by members of the Class.

247. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Vt. Stat. Ann. 9, § 2453, *et seq.,* with respect to purchases and/or reimbursements for purchases of Wellbutrin SR in the state of Vermont by members of the Class.

248. The class members have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for Wellbutrin SR prescription drugs than they would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of the above states and the District of Columbia were designed to prevent and flows from that which makes Defendants' conduct unlawful.

249. On behalf of the Class, Plaintiffs seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT FIVE

A. For Unfair And Deceptive Trade Practices Under State Law On Behalf Of Class Members In States Where Named Plaintiffs Did Not Purchase Or Provide Reimbursement for Wellbutrin SR.

250. This count is brought solely to preserve the appellate rights of the Plaintiffs in light of Judge Stengel's November 2, 2009 Memorandum and Order in this action.

251. This count is brought on behalf of a subclass comprised of all class members who purchased and/or provided reimbursement for Wellbutrin SR in the states of Alaska, Connecticut, Delaware, Hawaii, Kansas, Maine, Maryland, Montana, Nebraska, New Hampshire, New Mexico, North Dakota, Ohio, Oregon, South Carolina, South Dakota, Utah, Vermont,

Virginia, Washington and the District of Columbia, where the named Plaintiffs did not purchase and/or provide reimbursement for purchases of Wellbutrin SR . Plaintiffs allege that they are adequate class representatives for class members affected in these jurisdictions pursuant to Fed. R. Civ. P. 23.

252. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they filed baseless patent infringement actions against Eon and IMPAX and other generic manufacturers in order to prevent the FDA from granting final approval of pending applications of would-be competitors to market generic Wellbutrin SR. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, class members were deprived of the opportunity to purchase a generic version of Wellbutrin SR and Zyban, from March 1, 2002 until January 2004, and forced to pay higher prices for Buproprian Hydrochloride SR from January 2004 to June 30, 2006.

253. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq*.

254. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq*.

255. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*.

256. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D. C. Code § 28-3901, *et seq*.

257. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq*.

258. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq*.

259. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq*.

260. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq*.

261. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq*.

262. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq*.

263. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N. H. Rev. Stat. § 358-A:1, *et seq*.

264. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N. M. Stat. § 57-12-1, *et seq*.

265. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N. D. Cent. Code § 51-15-01, *et seq*.

266. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq*.

267. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq*.

268. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S. C. Code Laws § 39-5-10, *et seq*.

269. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S. D. Code Laws § 37-24-1, *et seq*.

270. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq*.

271. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq*.

272. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq*.

273. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq*.

274. The class members have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for Wellbutrin SR prescription drugs than they would have paid in the absence of these violations. This injury is of the type the referenced state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT SIX

A. For Unjust Enrichment Under State Law For Class Members In States Where Named Plaintiffs Did Not Purchase or Provide Reimbursement for Wellbutrin SR.

275. This count is brought solely to preserve the appellate rights of the Plaintiffs in light of Judge Stengel's November 2, 2009 Memorandum and Order in this action.

276. This count is brought on behalf of all class members who purchased and/or provided reimbursement for Wellbutrin SR in states where the named Plaintiffs did not purchase and/or provide reimbursement for purchases of Wellbutrin SR . Plaintiffs allege that they are

adequate class representatives for class members affected in these jurisdictions pursuant to Fed. R. Civ. P. 23.

277. Defendants have benefited from the monopoly profits on their sales of Wellbutrin SR resulting from the unlawful and inequitable acts alleged in this Complaint.

278. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Wellbutrin SR by members of the Class.

279. The Class has conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of the Class.

280. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for Wellbutrin SR is a direct and proximate result of Defendants' unlawful practices.

281. The financial benefits derived by Defendants rightfully belong to the Class, as the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

282. It would be inequitable and violative of the laws of the states named within this count concerning unjust enrichment for the Defendants to be permitted to retain any of the overcharges for Wellbutrin SR derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

283. Defendants should be compelled to disgorge in a common fund for the benefit of the Class all unlawful or inequitable proceeds received by them.

284. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to the Class.

285. The class members have no adequate remedy at law.

DEMAND FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

A. certifying the Class pursuant to the Federal Rules of Civil Procedure, certifying Plaintiffs as the representatives of the Class, and designating their counsel as counsel for the Class;

B. declaring the Defendants' conduct to be in violation of the antitrust and/or deceptive practice statutes in the Indirect Purchaser States;

C. granting Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

D. granting Plaintiffs and the Class damages as permitted by law;

E. granting Plaintiffs the right of disgorgement;

F. granting Plaintiffs and the Class their costs of prosecuting this action, together with interest and reasonable attorneys' fees, experts' fees and costs; and

G. granting such other relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: December 2, 2009

BARROWAY TOPAZ KESSLER MELTZER & CHECK, LLP

By: JHM6596

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EXHIBIT A

In re Wellbutrin SR Antitrust Litigation, No. 2:04-cv-5898-LS

State	IBEW Plan	Sheet Metal Workers Plan	UA Plan	AFL Plan	UFCW	Sidney Hillman Center	Exemplar States (California, Florida, Michigan, Minnesota, North Carolina, Tennessee)
Alabama					X		
Alaska							
Arizona					X		
Arkansas					X		
California					X		X
Colorado					X		
Connecticut							
Delaware							
DC							
Florida	X	X		X	X	X	X
Georgia			X				
Hawaii							
Idaho			X				
Illinois					X		
Indiana					X		
Iowa					X		
Kansas							
Kentucky					X		
Louisiana	X				X		
Maine							
Maryland							
Massachusetts	X						
Michigan					X		X
Minnesota					X		X
Mississippi							
Missouri	X				X		
Montana							
Nebraska							

State	IBEW Plan	Sheet Metal Workers Plan	UA Plan	AFL Plan	UFCW	Sidney Hillman Center	Exemplar States (California, Florida, Michigan, Minnesota, North Carolina, Tennessee)
Nevada					X		
New Hampshire							
New Jersey							
New Mexico							
New York						X	
North Carolina						X	X
North Dakota							
Ohio							
Oklahoma	X				X		
Oregon							
Pennsylvania					X		
Rhode Island			X				
South Carolina							
South Dakota							
Tennessee					X		
Texas			X				
Utah							
Vermont							
Virginia							
Washington							
West Virginia			X				
Wisconsin					X		
Wyoming							

Key – Shading indicates those states in which the named plaintiffs have purchased/reimbursed for Wellbutrin SR and in which by statute substantive state law affords a damages remedy to indirect purchasers.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Consolidated Second Amended End-Payor Class Action Complaint was served upon all counsel of record by electronic mail on this 2nd day of December, 2009.

By: /s/ JHM 8493
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